The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte EDWARD MANCILLA and
ELIZABETH M. LAGWINSKA

_____

Appeal No. 1999-1281
Application No. 08/712,249

_____

ON BRIEF

_____

Before WILLIAM F. SMITH, SPIEGEL, and ADAMS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 27-49, which are all the claims pending in the application.

Claims 27 is illustrative of the subject matter on appeal and is reproduced below:

> 27. An anticoagulant composition which does not adversely affect the measurement of calcium ion concentration within a blood sample produced by a process comprising
> (a) contacting an aqueous solution of sodium heparin with an acidic ion exchange resin for a period of time sufficient such that the aqueous effluent produce [sic] possesses a pH of about 3 or less;
> (b) reacting said effluent with a heavy metal-containing compound suitable to produce a heavy metal heparin salt;
> (c) reacting said heavy metal heparin salt produced in Step (b) with an aqueous solution of lithium salts in sufficient amounts such that the resulting solution exhibits a pH of about 6 to about 7.

The references relied upon by the examiner are

Eisenhardt et al. (Eisenhardt) 4,687,000 Aug. 18, 1987

(Celsus) "Heparin-Blood Collection and Analysis," Celsus Laboratories, Inc., Cincinnati, Ohio (1991)

GROUND OF REJECTION

Claim 27-49 stand rejected under 35 U.S.C. § 103 as being unpatentable over Eisenhardt in view of Celsus.

We reverse.

DISCUSSION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, and to the respective positions articulated by the appellants and the examiner. We make reference to the examiner's Answer[1] for the examiner's reasoning in support of the rejections. We

[1] Paper No. 24, mailed March 20, 1998.

further reference appellants' Brief[2] and appellants' Reply Brief[3] for the appellants' arguments in favor of patentability.

THE REJECTION UNDER 35 U.S.C. § 103:

According to the examiner (Answer, page 4) Eisenhardt "disclose that lithium salts of heparin are useful as anticoagulants" and that the lithium salt of heparin maybe used with other cations, however, Eisenhardt "do not state that the additional cation may be zinc, barium, or copper." The examiner finds (Answer, page 5) that Celsus "teaches that heparin zinc may also be used as an anticoagulant [and] … also indicates that the prior art had recognized that the use of heparin lithium as an anticoagulant lead [sic] to inaccurate values for blood calcium ion levels because $Ca^{2+}$ binds to heparin more strongly than does $Li^{+}$." The examiner further finds that "[a]ccording to … [Celsus] it was also known in the art that $Zn^{2+}$ has greater affinity for heparin than $Ca^{2+}$."

The examiner concludes (Answer, page 5) that since the art recognized that $Ca^{2+}$ binds heparin more strongly than $Li^{+}$, leading to inaccurate values for blood calcium ion levels, and $Zn^{2+}$ has greater affinity for heparin than $Ca^{2+}$, "[i]t would have been obvious for a person of ordinary skill in the art at the time of the invention … to provide an anticoagulant composition comprising a mixture of heparin salts which included lithium and heavy metal cations" [emphasis added].

[2] Paper No. 23, received November 17, 1997.
[3] Paper No. 25, received March 26, 1998.

The examiner argues (Answer, page 9) that "the specification appears to indicate that the order in which the cations are reacted with heparin is not critical." However, as set forth in In re Ochiai, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995) "an applicant [is entitled] to issuance of an otherwise proper patent unless the PTO establishes that the invention as claimed in the application is obvious over cited prior art, based on the specific comparison of that prior art with claim limitations." In contrast to the examiner's argument, appellants argue (Reply Brief, page 3):

> The claimed heparin composition is produced through a sequential and selective blocking and binding of heparin reactive sites. A first reaction utilizes a heavy metal, for example zinc or barium, to block calcium active sites on the heparin molecule. A second reaction then follows wherein lithium ions are utilized to bind those active sites which were not previously reacted with the heavy metal. Accordingly, the resultant heparin molecule so produced is "blocked" with **both** a heavy metal and e.g. a lithium salt.
>
> As set forth in [a]ppellants' specification, this process effectively limits the interaction of the heparin composition with any calcium ions which may be present in a blood sample to be assayed. This thereby obviates the need for added calcium or other artificial corrective steps to correctly assay calcium levels in an unknown sample.

Therefore, according to appellants, the order in which the cations are reacted with heparin is critical. The criticality of the process steps is also discussed in paragraph 7a of the Fiehler Declaration[4].

The examiner argues (Answer, page 6) that "[t]he claims are not deemed to be patentable over the prior art because appellants have merely provided a mixture

[4] Executed May 14, 1997, attached to the Brief as Exhibit B.

of two salts known to be useful independently as anticoagulants." The examiner then invokes (Answer, page 9) the principles of In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977), arguing that "[a]ppellants have not met the burden of establishing … that there is an unobvious distinction between the characteristics of the claimed compositions and those suggested by the prior art." However, as explained by appellants (Reply Brief, page 5):

> Appellants' claimed heparins are not a mixture of heparins, rather the heparin is a heavy metal salt-heparin salt. Given that [a]ppellants **multi-ion** heparins are neither disclosed nor suggested by the art, and thus no prima facie case of obviousness has been established, there is no shift in burden to provide evidence of "unexpected/superior results".

As set forth in Best "[w]here … the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical process, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product." On this record, as explained by appellants, and unlike the facts in Best, the claimed anticoagulant composition is neither identical nor substantially identical to the anticoagulant composition taught by the examiner's combination of references. In contrast to the mixture of heparins taught by the examiner's combination of references, the claimed anticoagulant composition is based on a heparin molecule "'blocked' with **both** a heavy metal and e.g. a lithium salt" [see, Reply Brief, page 3].

Therefore, we agree with appellants (Reply Brief, page 8) that "[n]o prima facie case has been made out and therefore the burden has not properly shifted to [a]ppellants to provide evidence of unexpected superior results."

The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). In our opinion, since the examiner's combination of references fail to teach a heparin molecule having more than one metal salt thereon, the examiner has not meet her burden of establishing a prima facie case of obviousness under 35 U.S.C. § 103.

Where the examiner fails to establish a prima facie case, the rejection is improper and will be overturned. In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Accordingly, we reverse the examiner's rejection of claims 27-49 under 35 U.S.C. § 103.

Having determined that the examiner has not established a prima facie case of obviousness, we find it unnecessary to discuss appellants evidence of unexpected results relied on by appellants to rebut any such prima facie case.

REVERSED

| | |
|---|---|
| | ) |
| William F. Smith | ) |
| Administrative Patent Judge | ) |
| | ) |
| | ) |
| | ) BOARD OF PATENT |
| Carol A. Spiegel | ) |
| Administrative Patent Judge | ) APPEALS AND |

)
) INTERFERENCES
)
Donald E. Adams )
Administrative Patent Judge )

Montgomery W. Smith
American Home Products Corporation
1915 Olive St.
St. Louis, MO 63103

ED